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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,774	12/02/2003	Warren Finlay	034343-2	9435

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NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER	
BUNIN, ANDREW M	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,774	FINLAY ET AL.	
	Examiner	Art Unit	
	Andrew M. Bunin	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the straight diffuser claimed in claim 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keane et al. (US 6748947) in view of Britto et al. (US 6098619). Keane et al. disclose a device for deagglomerating powder agglomerates that has a chamber 14 adapted for fluid circulation. In addition, Keane et al. disclose an inlet 22 interconnecting the chamber 14 and a powder source for supplying the chamber with powder agglomerates entrained in a flow of gas. Figures 1, 5, and 6 display the powder agglomerates and the flow of gas defining a swirling fluid flow inside the chamber 14 where the powder agglomerates are subjected to at least one of turbulence, shear force fluidizing, collisions with other ones of the powder agglomerates, and collisions with a surface of the chamber (all Figures). Keane et al. continue to disclose an outlet 32 having a longitudinal axis 4 (arrow exiting outlet 32 in Figure 5) and being connected to the chamber 14 for inhalation such that the swirling fluid flow in the chamber 14 can swirl about the longitudinal axis of the outlet 32 and can exit from the chamber 14 as a longitudinal fluid flow 4 (arrow exiting outlet 32 in Figure 5) and secondary fluid flow 4A (Figure 6). Keane et al. also disclose the longitudinal fluid flow 4 being directed along the longitudinal axis of the outlet 32, and the secondary fluid flow 4A or 4 being directed away from the longitudinal axis of the outlet 32. Keane et al. designates the fluid flow

with numerals 2-4 which demonstrate how the flow swirls around in many directions along the x, y, and z axes before exiting the device. Therefore, the device of Keane et al. teaches the device as being capable of producing the secondary and longitudinal flows as taught in Figure 2 of the instant application. Keane et al. disclose everything except the feature of a mesh in the outlet for preventing powder agglomerates above a predetermined size from traversing the mesh. However, Britto et al. disclose a similar inhaler apparatus for deagglomerating powder agglomerates for inhalation including a mesh D in an outlet 20 for preventing powder agglomerates above a predetermined size from traversing the mesh, and capable of reducing the secondary fluid flow relative to the longitudinal fluid flow exiting from the chamber to thereby reduce powder deposition in a mouth and throat of a user. In addition, the mesh D is positioned near a base of the outlet 20 that is adjacent to the surface of the chamber so that most of the powder agglomerates in the chamber collide with the mesh at an oblique angle. Since the powder is being spun around in a vertical flow, these particles will collide with the mesh at an oblique angle and assist in deagglomerating the powder agglomerates inside the chamber. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Keane et al. with the mesh screen taught by Britto et al. in order to break up agglomerated drug particles and increasing fine particle mass.

As for claim 3, the chamber 14 is a cyclone chamber having a disc-shaped portion (Figure 6), the inlet 22 having a longitudinal axis 4A that is perpendicular with respect to the longitudinal axis 4 of the outlet 32 as shown in Figures 1, 2, and 6. The

axis of the inlet 22 is offset from the longitudinal axis of the outlet 20 so that an inner surface at the base of the inlet 22 is tangential with respect to the surface of the chamber 14. As shown in Figure 3, inlet 22 is slightly offset (axis 6) from the outlet 32 causing the longitudinal axis of the inlet 22 to be offset from longitudinal axis of the outlet 32.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keane et al. in view of Britto et al. Keane et al. further disclose outlet 32 acting as a mouthpiece having a first end (outlet port) and a second end being insertable in the mouth of the user (column 4, lines 25-30). In addition, the mesh D taught by Britto et al. is connected to a first end 14 of a mouthpiece 20. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Keane et al. with the mesh screen taught by Britto et al. in order to break up agglomerated drug particles and increasing fine particle mass.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable Keane et al. in view of Britto et al. Although it isn't disclosed that the mesh has a pore size of less than 250 um or a pore size of the mesh ranging between 30 to 150 um, it would have been obvious to one having ordinary skill at the time of the invention to vary the design disclosed by Britto et al. to fit these ranges in order to meet the needs of different patients. It is crucial for a medication to be placed at certain locations in the lungs depending on the drug's purpose. Therefore, the size of the powder will vary depending on where it is supposed to be placed in the lungs. Smaller sized powder particles move

further into the lungs, therefore, the size of the mesh pore would be varied in order to deagglomerate the powder to a desired size. In addition, Britto et al. states, "particles suitable for respiration have an aerodynamic diameter between 0.5 and 10 um." (column 7, lines 5-7) Therefore, the mesh pore size must be at least less than 250 um to meet this range.

Keane et al. also doesn't disclose the inlet 22 having an internal diameter of 5 to 7 mm and the outlet 32 having an internal diameter of 8 to 12 mm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the diameter sizes of the inlet and outlet because Applicant has not disclosed that an inlet internal diameter of 5-7 mm and an outlet internal diameter of 8-12 mm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the diameter used for Keane et al. device because the diameter may be varied for patients of different ages or for different drug purposes. Depending on the drug, the diameter of the outlet and/or inlet would need to be a certain size to limit the amount of medication delivered as well as vary the speed at which the medication leaves the outlet. Therefore, it would have been obvious matter of design choice to modify Keane et al. to obtain the invention as specified in claim 6.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keane et al. in view of Britto et al. Although Keane et al. and Britto et al. don't directly disclose a

mouthpiece including a straight diffuser with a 13 to 15 degrees deflection. A diffuser can be considered a type of baffle or a "flow passage...that decelerates a stream of gas or liquid from a high to a low velocity" (dictionary.com). However, Britto et al. teach section 34 or section 38, which read on the definition of a diffuser with about 13-15 degrees of deflection. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Keane et al. with the straight diffuser taught by Britto et al. in order to

The internal diameter of 15-25 mm and length of 5-25 mm would be considered an obvious matter of design choice to a person of ordinary skill in the art at the time of the invention to vary the diameter and length of Keane et al. device to fit these ranges because Applicant has not disclosed that mouthpiece having an internal diameter of 15-25 mm and length of 5-25 mm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a variety of diameter and lengths depending on the patient's mouth size because changing the length or diameter can depend on the whether the patient is an adult, child, or infant as well as the medicament used can depend on the mouthpiece having a certain diameter.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keane et al. in view of Britto et al. These method steps would have been obvious to one having ordinary skill in the art at the time of the invention since they would have

resulted in the use of the device disclosed by Keane et al. in view of Britto et al. as explained in the rejections of claims 1-9.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection. Keane et al. (US 6748947) disclose an inlet 22 (dry powder supply port) interconnecting a chamber 14 and a powder source as shown in Figures 1 and 3. In addition, Keane et al. teach the powder as swirling about the longitudinal axis of the outlet.

Keane et al. designates the fluid flow with numerals 2-4 which demonstrate how the flow swirls around in many directions along the x, y, and z axes before exiting the device. Therefore, the device of Keane et al. is capable of producing the secondary and longitudinal flows as taught in Figure 2 of the instant application. In response to applicant's argument of powder not swirling about the longitudinal axis of the outlet, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6029661, US 6427688, and US 4940051

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMB
2/16/06

Henry Bennett
Supervisory Patent Examiner
Group 3700